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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Docket No: Q65805

HIRAYAMA, Kouji, et al.

Appln. No.: 09/933,000

Group Art Unit: 1743

Confirmation No.: 6965

Examiner: Lyle Alexander

Filed: August 21, 2001

For: TEST APPARATUS FOR ASSAYING A COMPONENT IN A LIQUID SAMPLE

SUBMISSION OF APPELLANTS' BRIEF ON APPEAL

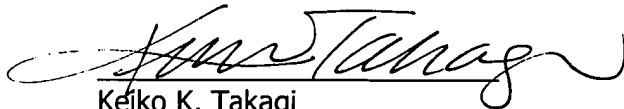
MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an original and two copies of Appellant's Brief on Appeal. A check for the statutory fee of \$330.00 is attached. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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23373

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Date: March 1, 2004 (timely filed since February 28, 2004 was a Sunday)



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APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

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Sir:

APPELLANT'S BRIEF ON APPEAL

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**APPELLANTS' BRIEF ON APPEAL
UNDER 37 C.F.R. § 1.192
U.S. Appln. No. 09/933,000**



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**APPELLANTS' BRIEF ON APPEAL
UNDER 37 C.F.R. § 1.192
U.S. Appln. No. 09/933,000**



REAL PARTY OF INTEREST

The real party in interest is Kyoto Daiichi Kagaku Co., Ltd., by virtue of an assignment.

RELATED APPEALS AND INTERFERENCES

Appellant, Appellant's legal representative, and the Assignee in this application are not aware of any other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 11-17 were originally pending in the present application. Claim 11 was amended in an Amendment under 37 C.F.R. § 1.116 filed on March 24, 2003. Claims 11-17 on appeal are set forth in their entirety in the Appendix attached herewith.

STATUS OF AMENDMENT

A Response under 37 C.F.R. § 1.111 was filed on August 11, 2003, which has been entered.

SUMMARY OF THE INVENTION

The present invention relates to a test apparatus for assaying a component in a liquid sample by measuring a reflected light having a support defining an upper side and a lower side and having one of a through hole and a light permeable area, a reagent layer defining an upper side and a lower side and having a detecting area, and a cover including a lower side facing the reagent layer and which covers at least the detecting area. *See* page 5, line 25 to page 6, line

7. The reagent layer is fixed on the upper side of the support to cover one of the through hole and light permeable area. *See* page 6, lines 5-6. At least a portion of the cover covering the detecting area is black. *See* page 10, lines 20-23.

The test apparatus of the present invention can be used with liquid samples, such as whole blood, and the reagent layer of the present invention is responsive to a component of the liquid sample. *See* page 7, lines 9-12. The measurement is carried out by observing the porous membrane from the support side (i.e., and reflected light is measured from the lower side of both the reagent layer and the cover). *See* page 7, lines 12-13.

In addition, the cover is fixed on the support in such a manner that a gap exists between the cover and the reagent layer, and the cover has a sample-supplying hole and an air exhaust hole. *See* page 6, lines 22-25 and Figure 2. Further, the cover of the present invention can contact one side of the reagent layer opposite to the support. *See* page 7, lines 14-16 and Figure 3. The reagent layer includes light reflective particles. *See* page 9, lines 21-25.

The present invention can also include a light reflection layer in contact with the reagent layer and/or a porous membrane disposed between the reagent layer and the support. *See* page 8, line 13 to page 9, line 3.

ISSUES

Whether claims 11-17 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 4-188065 (hereinafter "JP '065") in view of EP 0 587 222 A2 (hereinafter "EP '222").

GROUPING OF CLAIMS

The claims do not stand or fall together.

Claims 11-12 and 16-17 stand or fall together.

Claims 13-15 stand or fall together.¹

ARGUMENT

A. The Examiner's Position

For the Board's convenience, the Examiner's positions, as set forth on pages 2-4 of the Office Action dated February 21, 2002, pages 4-5 of the Office Action dated April 9, 2003 and page 2 of the Office Action dated October 28, 2003, are reproduced below.

1. Office Action dated February 21, 2002

Claims 11-17 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Applicants admitted prior art on page 6 in reference to JP-A-4-188065.

Applicants state on page 6 "The test apparatus for use in the present invention can have the following embodiments. One of them is a test apparatus having the same basic structure disclosed in JP-4-188065..."

Applicants have stated JP-4-188065 has the same structure as presently claimed. Clarification could be achieved by citing JP-4-188065 in the response to this office action and discussing what JP-4-188065 teaches compared to the pending claims.

2. Office Action dated April 9, 2003

Claims 11-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP-A-4-188065 (references as JP hereafter) in view of EP 0587222 (references as EP hereafter).

¹ See Argument at page 8.

See the appropriate paragraph of paper 7 for the teachings of JP.

In light of the 3/24/03 translation of the JP supplied by Applicants, the Office concurs with Applicants characterization of JP that it lacks a teaching of a black cover.

EP teaches a test apparatus for the analysis of a liquid. Figures 1-2 teach a support (12) with an aperture and support member (13) that is read on the claimed "support...having a through hole and light permeable area". A reagent layer (14) is on the upper side of the support member (13) and cover (17) that faces the reagent layer (14). Page 6 lines 54+ teach a black pigmented means can be used between the absorbent area and the read area that has been read on the claimed black portion of the cover.

One having ordinary skill in the art may possess a fundamental knowledge that black absorbs light over a broad range of wavelengths. Furthermore, EP (page 6) teaches an apparatus in the same filed [sic] of endeavor using a light absorbing material having a black cover in order to fully absorb all lights that interferes with the measured or tested light.

Thus, it would have been obvious to one having ordinary skill in the art to modify the test apparatus of JP in view of EP and substitute a cover which absorbs light at all wave lengths, such as a black cover as taught by EP, to gain the advantage of permitting the cover to absorb light over a wider range of wavelengths.

3. Office Action dated October 28, 2003

Claims 11-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over JP-A-4-188065 (references as JP hereafter) in view of EP 0587222 (references as EP hereafter).

See the appropriate paragraph of paper 12.

Applicant's arguments filed 8/26/03 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants assert EP fails to disclose a cover (17) is above a reading area and that the cover can be black. EP teaches on page 6 lines 45-53 an absorbing means positioned between the absorbent material (16) and the read area to prevent background interference. This is the motivation used to modify JP to teach a black cover.

B. Appellant's Response

Appellants respectfully submit that the embodiments of the present invention according to claims 11-17 are not obvious.

Claim 11 is directed to a test apparatus for assaying a component in a liquid sample by measuring a reflected light, comprising: a support defining an upper side and a lower side and having one of a through hole and a light permeable area, a reagent layer defining an upper side and a lower side and having a detecting area, the reagent layer being fixed on the upper side of the support to cover one of the through hole and light permeable area, and a cover including a lower side facing the reagent layer and which covers at least the detecting area. At least a portion of the cover covering the detecting area is black and reflected light is measured from the lower side of both the reagent layer and the cover.

The Examiner asserts that EP '222 discloses a cover (17) that faces the reagent layer (14).

However, the cover of EP '222 is formed above the absorbent material (16), which is positioned adjacent to at least a portion of the periphery of reading area (15), and a portion of the cover appears to have a lower face facing the reagent layer (14). *See Fig. 1.* Therefore, the cover is above the absorbent material (16), and the cover does not cover the reading area (15), which corresponds to the detecting area of the present invention.

Next, the Examiner takes the position that EP '222 teaches that an absorbing means can be positioned between the absorbent material (16) and the read area (15).

EP '222 discloses that a light absorbing or reflecting means (19) can be positioned between the absorbent material and the read area. *See* page 6, lines 54-56 and Fig. 2. However, the light absorbing or reflecting means positioned between the absorbent material and the read area does not correspond to a cover (17) nor is it located above the reading area. *Id.*

Further, the Examiner takes the position that since EP '222 teaches a black absorbent material, one of ordinary skill in the art would have been motivated to modify the cover of JP '065 to be black.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching, suggestion or incentive supporting the combination. *See* MPEP 2143.

EP '222 discloses that the absorbent material may be entirely comprised of the light absorbing or reflecting material or color, and discloses that the absorbent material may be black (page 45, lines 48-53). However, as noted above, the light absorbing or reflecting material does not correspond to the cover (17), but to the absorbent material (16) in Fig. 1 and 2. Since EP '222 does not disclose a cover over the reading area or that the cover can be black, EP '222 does not provide any incentive for modifying the cover of JP '065.

In addition, the absorbent material (16) of EP '222 takes up (absorbs) wash fluid (22), which contains soluble interferents and unbound label, away from read area (15). *See* page 6, lines 34-35, that as shown in Fig. 4. Therefore, in order to avoid the influences of fluorescence and luminescence by soluble interferents and unbound label in the measurement of a sample,

black materials are used in the absorbent material (16). In other words, EP '222 discloses black as a color of absorbed material in order to block signals generated by unnecessary chemiluminescent or fluorescent label and the like. Further, at page 7, lines 2-6, EP '222 discloses that "it is understood that the light absorbing or reflecting material is to be included in the element in a manner to absorb or block signals generated by washed label and other interferents from outside the read area prior to it moving back into the read area."

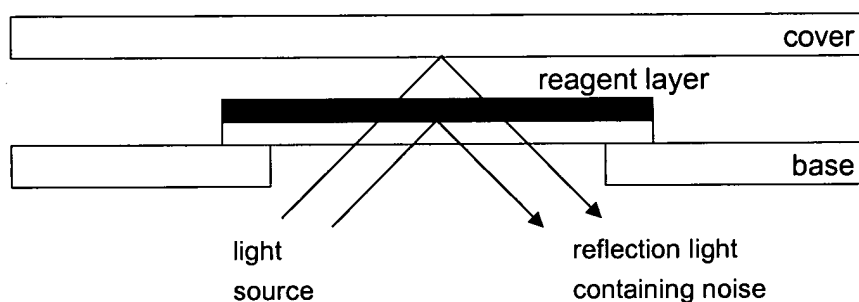
Accordingly, EP '222 neither discloses nor suggests the concept of a cover that absorbs stray light passed through a reagent layer as in the present invention. Therefore, EP '222 does not provide any benefit or advantage of using black absorbing material in a cover, and provides no motivation to modifying the cover of JP '065.

Again, Appellants stress that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination, and that a teaching by itself is not sufficient to provide motivation for one of ordinary skill in the art to arrive at claimed invention. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

In this case, EP '222 does not provide any technical motivation that would lead one of ordinary skill in the art to specifically use a black cover. Since EP '222 fails to teach a cover above the reading area, does not disclose that cover (17) can be black, and does not disclose any advantage of using a black cover to absorb light because the light for measurement is not reflected in the invention of EP '222 due to the particular structure of the analytical element,

one of ordinary skill in the art would not be motivated to modify the cover of JP '065 so that it is black based on the disclosure of EP '222.

Even assuming, *arguendo*, that there was some motivation to combine JP '065 and EP '222, since EP '222 only discloses a black light absorbing material, the resulting structure would have the following structure:



In contrast, in the present invention, at least a portion of the cover covering the detecting area is black, and reflection light containing no noise is observed because the stray light passed through the reagent layer is absorbed by the black cover. Therefore, even if the references were somehow combined, one of ordinary skill in the art would not arrive at the present invention.

In view of the foregoing, it is respectfully submitted that the present invention is not *prima facie* obvious in view of JP '065 and EP '222.

In addition, claims 13-15 are separately patentable because neither JP '065 nor EP '222 disclose a cover or a light reflection layer that contacts a reagent layer on a side opposite to the support, or a reagent layer containing light reflective particles.

**APPELLANTS' BRIEF ON APPEAL
UNDER 37 C.F.R. § 1.192
U.S. Appl. No.: 09/933,000**

Attorney Docket No.: Q65805

In summary, Appellants respectfully submit that JP '065 in view of EP '222 fail to teach or suggest the present invention.

Conclusion

In view of the above, Appellants submit that the Examiner's rejections are improper and should be reversed.

Favorable consideration is respectfully requested.

The present Brief on Appeal is being filed in triplicate. Unless a check is submitted herewith for the fee required under 37 C.F.R. §1.192(a) and 1.17(c), please charge said fee to Deposit Account No. 19-4880.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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APPENDIX

CLAIMS 11-17 ON APPEAL:

Claim 11 (previously presented): A test apparatus for assaying a component in a liquid sample by measuring a reflected light, comprising:

a support defining an upper side and a lower side and having one of a through hole and a light permeable area,

a reagent layer defining an upper side and a lower side and having a detecting area, the reagent layer being fixed on the upper side of the support to cover one of the through hole and light permeable area, and

a cover including a lower side facing the reagent layer and which covers at least the detecting area,

wherein at least a portion of said cover covering the detecting area is black; and

wherein said reflected light is measured from the lower side of both the reagent layer and the cover.

Claim 12 (previously presented) The test apparatus as claimed in claim 11, wherein said cover is fixed on the support in such a manner that a gap exists between the cover and the reagent layer, and said cover has a sample-supplying hole and an air exhaust hole.

Claim 13. (previously presented) The test apparatus as claimed in claim 11, wherein said cover contacts one side of the reagent layer opposite to the support.

Claim 14 (previously presented) The test apparatus as claimed in claim 11, further

APPENDIX

comprising a light reflection layer in contact with the reagent layer.

Claim 15 (previously presented) The test apparatus as claimed in claim 11, wherein said reagent layer comprises light reflective particles.

Claim 16 (previously presented) The test apparatus as claimed in claim 11, wherein the liquid sample is whole blood and said reagent is responsive to a component of said blood.

Claim 17 (previously presented) The test apparatus as claimed in claim 11, further comprising a porous membrane disposed between the reagent layer and the support.